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| APPLICATION NO.   | FILING DATE          | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|----------------------|----------------------|---------------------|------------------|
| 10/791,916  | 03/03/2004           | Hugh R. Sharkey      | 33108-703.201       | 3842             |
| 21971 7590 01/26/2007 WILSON SONSINI GOODRICH & ROSATI 650 PAGE MILL ROAD |                      |                      | EXAMINER            |                  |
|   |                      |                      | STEWART, ALVIN J    |                  |
| PALO ALTO, CA 94304-1050  |                      | •                    | ART UNIT            | PAPER NUMBER     |
| •   |                      |                      | 3738                |                  |
|   |                      |                      |                     |                  |
| SHORTENED STATUTOR  | Y PERIOD OF RESPONSE | MAIL DATE            | DELIVERY MODE       |                  |
| 3 MONTHS  |                      | 01/26/2007           | PAPER               |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

|  | Application No.   | Applicant(s)   |  |  |  |
|--|---|----------------|--|--|--|
|  | 10/791,916  | SHARKEY ET AL. |  |  |  |
| Office Action Summary  | Examiner  | Art Unit       |  |  |  |
|  | Alvin J. Stewart  | 3738           |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply   |   |                |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |                |  |  |  |
| Status   |   |                |  |  |  |
| 1) Responsive to communication(s) filed on 12/1.   | <u>2/6</u> .  |                |  |  |  |
| 2a) ☐ This action is <b>FINAL</b> . 2b) ☑ This   | This action is <b>FINAL</b> . 2b)⊠ This action is non-final.  |                |  |  |  |
| 3) Since this application is in condition for allowa   | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is |                |  |  |  |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  |   |                |  |  |  |
| Disposition of Claims  |   |                |  |  |  |
| <ul> <li>4)  Claim(s) 1-7.11-26.32-38.40.46-51.53.54.60-67.71 and 72 is/are pending in the application.</li> <li>4a) Of the above claim(s) is/are withdrawn from consideration.</li> <li>5)  Claim(s) 47-51, 62-66 and 72 is/are allowed.</li> <li>6)  Claim(s) 1-7.11-26.32-38.40.46.53.54.60.61.67 and 70 is/are rejected.</li> <li>7)  Claim(s) is/are objected to.</li> <li>8)  Claim(s) are subject to restriction and/or election requirement.</li> </ul>  |   |                |  |  |  |
| Application Papers   |   |                |  |  |  |
| 9) ☐ The specification is objected to by the Examiner.  10) ☑ The drawing(s) filed on 19 July 2004 is/are: a) ☑ accepted or b) ☐ objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |   |                |  |  |  |
| Priority under 35 U.S.C. § 119   |   |                |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.  |   |                |  |  |  |
| Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  Paper No(s)/Mail Date   | 4) Interview Summary Paper No(s)/Mail D 5) Notice of Informal F 6) Other:                                       |                |  |  |  |

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#### **DETAILED ACTION**

### Response to Arguments

Applicant's arguments filed 12/12/06 have been fully considered but they are not persuasive.

The Examiner understands the Applicant's representative point of view. However, the claims read on the reference because the Examiner still believes that the Van Tassel et al reference reads on the independent claims. Van Tassel et al discloses all the structure limitations of the applicant's invention. In Figures 14-18, discloses an inflatable partitioning element comprising a hollow interior adapted to contain an inflation fluid and an inflation port communicating with the hollow interior. See below to see rejection.

Regarding the Van Tassel et al reference, the Examiner believes that the reference still read on the rejected claims. For example, the Examiner is giving patentable weight to the structure limitations on the claims but is not giving patentable weight to the functional language disclosed in the claims, such as the words "for treating...", "configured to", "for increasing...", etc.. For this type of wording the examiner has considered those words but the Examiner has not given patentable weight to them.

The Examiner has interpreted the claims as follow: the inflatable partitioning element is element (402), the hollow interior is shown in Figure 15, the inflation port is element (see Fig. 15) and the at least one anchoring element is the surface of element 402 or element (40). The device is capable of being inserted in the ventricular chamber having the inflatable portion 402 facing the mitral valve as shown in figure 2 of the Applicant's invention in order to divide the ventricular chamber into a main productive portion and a secondary, non-productive portion.

In order to overcome the rejection the Applicant's representative has to add more structure limitations to the independent claims.

Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

In order to be given patentable weight, a functional recitation must be supported by recitation in the claim of sufficient structure to warrant the presence of the functional language.

In re Fuller, 1929 C.D. 172; 388 O.G. 279.

Claims are being treated as product by process claims. In accordance with MPEP 2113, these claims are not limited to the manipulations of the recited steps, only the structure implied by the steps.

This phrase has been identified as an intended use limitation because is typical of claim limitations which may not distinguish over prior art according to the principle. It has been held that the recitation that an element is "configured to" performing a function is not a positive limitation but only requires the ability to so perform.

Finally, the word "partitioning" has not been given patentable weight and is only part of the structure name.

### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

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international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5-7, 11-26, 32-35, 38, 40, 46, 53, 54, 60, 61, 67 and 71 are rejected under 35 U.S.C. 102(e) as being anticipated by Van Tassel et al US Patent 6,652,555 B1.

Van Tassel et al discloses an inflatable partitioning element (see the whole device in Fig. 14) having an outer periphery, a hollow interior ((see Fig. 15) containing an inflation fluid (see Figs. 17 & 18), an inflation port (see Fig. 15) communicating with the hollow interior, a hub (408), a supporting element (404), at least one anchoring element (the anchor can be the outer surface of element 402 and/or element 40) and a valve (426).

Regarding the functional language disclosed in most of the claims, in order to be given patentable weight, a functional recitation must be supported by recitation in the claim of sufficient structure to warrant the presence of the functional language. *In re Fuller, 1929 C.D.* 172; 388 O.G. 279.

Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "Apparatus claims cover what a device *is*, not what a device *does.*" *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990).

It has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense.

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In claims 1, 21, line 3, it has been held that the recitation that an element is "configured to" performing a function is not a positive limitation but only requires the ability to so perform.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4, 20, 36, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Tassel et al US Patent 6,652,555 B1 in view of Khairkhahan et al US Patent 2006/0264980 A1.

Van Tassel et al discloses the invention substantially as claimed. However, Van Hassel et al does not disclose a plurality of barbs on the periphery of the inflatable partitioning element.

Khairkhahan et al teaches an implant comprising a system for improving cardiac function having a plurality of barbs around the periphery of the inflatable partitioning element in order to hold the implant in place (see paragraph 167).

#### Allowable Subject Matter

Claims 47-51, 62-66 and 72 are allowed.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J. Stewart whose telephone number is 571-272-4760. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ALVIN J. STEWART PRIMARY EXAMINER Art Unit 3738

A. Strat

January 15, 2007.